K060819

JUN 16 2006

The Medical House	Medical House Products Limited	
Pre-market Notification	**Section 5.0**	Revision No :01
Product: cool.click 2™	**510(k) Summary**	Effective Date: 22 March 2006

510(k) Summary [As required by 21 CFR 907.92(a)]

A. Submitter Information:

Submitter: Medical House Products Limited
199, Newhall Road
Sheffield, S9 2QJ
United Kingdom

Contact person: Rose Y Guang
Quality Assurance and Regulatory Affairs Manager
E-mail: rguang@themedicalhouse.com
Phone: (+44) 1142619011
Fax: (+44) 1142431597

Date: March 22 2006

B. Device Information

Trade/Proprietary Name: cool.click 2™

Common Name: Needle-free Injector, Jet Injector

Classification Name: Jet Injector, Non-Electrically Powered Fluid Injector

Predicate Devices: cool.click K050734
Serojet K003908
Clicker K994384
Reconstitution Kit & Vial Connector K010623

Device Description: cool.click 2™ is a needle-free delivery device for Serono growth hormone products. The device delivers the drug product by firing a jet of liquid directly through the skin to the subcutaneous region. The jet is created via a powerful spring acting on a piston inside the nozzle and the liquid is forced out through a small aperture at high speed, creating a very fine, high pressure stream of drug that penetrates the skin.

The Medical House	Medical House Products Limited	
Pre-market Notification	**Section 5.0**	Revision No :01
Product: cool.click 2™	**510(k) Summary**	Effective Date: 22 March 2006

Intended Use: The cool.click 2™ Needle-free Growth Hormone Delivery System is indicated for the administration of Serono's growth hormone drug products and is intended for home use by patients authorized by their physicians to self-inject.

C. **Comparison of Required technological characteristics:**

cool.click 2™ Needle-Free Growth Hormone Delivery System applies the same technological characteristics as the predicated devices. It is designed similarly to the devices that are currently marked in the U. S.

The key difference of the cool.click 2™ Needle-Free Growth Hormone Delivery System is it has a digital display to provide more clear and accurate information to users.

Due to the technological identity and the same indications for use of cool.click 2™ Needle-Free Growth Hormone Delivery System and predicated devices, no additional safety items were identified.

D. **Summary and conclusion of performance tests:**

Extensive design verification, functional and performance testing have been conducted. The information provided in this premarket notification demonstrates that the cool.click 2™ Needle-Free Growth Hormone Delivery System is safe and effective for the intended use and is substantially equivalent to the legally marketed predicate devices.

The Medical House	Medical House Products Limited	
Pre-market Notification	**Section 4.0**	Revision No :01
Product: cool.click 2™	**Indication for Use Statement**	Effective Date: 22 March 2006

510(k) Number: K060819
Device Name: cool.click 2™ Needle-free Growth Hormone Delivery System

Indications for Use:
The cool.click 2™ Needle-free Growth Hormone Delivery System is indicated for the administration of Serono's growth hormone drug products and is intended for home use by patients authorized by their physicians to self-inject.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 2006

Ms. Rose Y. Guang
Quality Assurance & Regulatory Affairs Manager
Medical House Products Limited
199 Newhall Road
Sheffield,
United Kingdom S9 2QJ

Re: K060819
Trade/Device Name: Cool.Click 2 Needle-Free Growth Hormone Delivery System
Regulation Number: 880.5430
Regulation Name: Nonelectrically Powered Fluid Injector
Regulatory Class: II
Product Code: KZE
Dated: March 22, 2006
Received: March 27, 2006

Dear Ms. Guang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

The Medical House	Medical House Products Limited	
Pre-market Notification	**Section 4.0**	Revision No :01
Product: cool.click 2™	**Indication for Use Statement**	Effective Date: 22 March 2006

510(k) Number: _____
Device Name: cool.click 2™ Needle-free Growth Hormone Delivery System

Indications for Use:
The cool.click 2™ Needle-free Growth Hormone Delivery System is indicated for the administration of Serono's growth hormone drug products and is intended for home use by patients authorized by their physicians to self-inject.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
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Concurrence of CDRH, Office of Device Evaluation (ODE)

...ion Sign-Off)
...n of Anesthesiology, General Hospital,
...ion Control, Dental Devices

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